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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,308	03/30/2004	Luca Battistini	GRT/4865-38	1799

23117 7590 10/28/2008
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EXAMINER	
RAE, CHARLESWORTH E	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
10/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/812,308	BATTISTINI ET AL.	
	Examiner	Art Unit	
	CHARLESWORTH RAE	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, filed 07/07/08, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of actions being applied to the instant application.

This action is made final.

Status of the Claims

Claims 9-11 are currently pending in this application.

Response to applicant's arguments/remarks

Rejections under 103(a)

a) The rejection based on Rossi and Hashimoto or Lenardo, in further view of Kawahito et al., is withdrawn.

b) The rejection based on Mistrella et al. and Hashimoto et al. or Lenardo is maintained as applicant's arguments are not found to be sufficiently persuasive to overcome the rejection for the reasons previously made of record in the Office action mailed 04/04/08, at pages 3-5 (see applicant's Response, received 07/07/08, at pages 3-7) and for the additional reasons set forth below:

It is the examiner's position that it would have been obvious to a person of skill in the art at the time the invention was made to treat a mammal, including a human, with an autoimmune disease (e.g. uveitis) as taught separately by Hashimoto et al. and

Lenardo by administering DL111-IT (= STI959) as taught by Mistrello et al. to suppress the immune system (i.e. immunosuppressant effect). One would have been motivated to treat an autoimmune disease (e.g. uveitis) in a mammal in need of said treatment with DLT111-IT because Mistrella et al. suggest that there is a need for more selective and less toxic immunosuppressant agents, as well as teach a mice model that is predictive for treating autoimmune diseases, while Hashimoto et al. and Lenardo separately suggest that immunosuppressant drugs that are useful in treating autoimmune disorders (e.g. rheumatoid arthritis) may also be useful for treating uveitis.

With respect to the preamble, Mistrella et al. teach the instant immunosuppressant drug i.e. DL111-IT (= ST1959) in a dose that overlaps with the dose of DL111-IT (= ST1959) disclosed in the instant application such that administering said DL111-IT (= ST1959) in said dose to a mammal (e.g. human) with an autoimmune disease (e.g. uveitis) would necessarily induce immunosuppression. To the extent that the cited art teach all of the instant claimed limitations, it is capable of performing the intended function.

Thus, it would have been obvious to a person of skill in the art at the time the invention was made to create the instant claimed invention with reasonable predictability.

Claim rejections – 35 USC 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9-11 are rejected under 103(a) as being unpatentable over Mistrello et al. (already made of record by applicant) and Hashimoto et al. (GB 2246350A) or alternatively Mistrello et al. and Lenardo (WO 94/28926).

Claim 9 recites "[a] method for treating uveitis in a subject in need thereof, comprising administering 3-(2-ethylphenyl)-5-(3-methoxyphenyl)-l l-l-1,2,4-triazole to

said subject." Claim 10 recites "wherein said subject is a mammal." Claim 11 recites "wherein said subject is a human."

Mistrello et al. teach DL111-IT (= ST1959) is an immunosuppressive agent effective in inhibiting the antibody response to both thymus-dependent (SRBC) and thymus-independent (LPS) antigen (page 168, see discussion section, especially col. 1, first full para). Mistrello et al. teach a method of treating an autoimmune disorder in a DBA female mice comprising administering DL111-IT (= ST1959), for example, wherein the DL111-IT was dissolved in sesame oil and injected subcutaneously on a mg/kg basis at various doses ranging from 1 mg/kg to 25 mg/kg (pages 163-166, especially Results section), which overlaps with the instant claimed active method step of administering ST1959 to a subject need thereof (i.e. ST1959 dissolved in sesame oil and administered subcutaneously to EAU rats at a dose of 0.5 mg/kg/day; see instant specification, pages 14-16). Mistrello et al. exemplify a method of treatment comprising administering DLIII-IT in a dose of 5 mg/kg via injection to adjuvant arthritic rats, which resulted in a marked reduction of foot pad swelling (pages 164 to 166, especially page 166, section entitled "Effect on DTH"). Mistrello et al. teach that the majority of immunosuppressant drugs in medicine were originally developed for treating cancer and only later were found to be useful as immunosuppresants and that there is therefore a need for more selective immunosuppressants with less toxic profiles (page 163, introduction section, especially col. 1). However, Mistrella et al. do not teach the instant method of treating uveitis.

Hashimoto et al. (GB 2246350A) is added to show that immunosuppressant drugs used to treat rheumatoid arthritis are also used to treat uveitis. Hashimoto et al teach methods of treatment comprising certain tricyclic macrolide compounds that possess immunosuppressive properties for treating autoimmune diseases, including rheumatoid arthritis and uveitis (page 8, lines 22-34).

Alternatively, Lenardo (WO 94/28926) is added to also show that immunosuppressant drugs used to treat rheumatoid arthritis are also used to treat uveitis. Lenardo teach methods of treating autoimmune diseases such as uveitis and arthritis in animals and humans (see abstract and page 5, last para.)

It would have been obvious to a person of skill in the art at the time the invention was made to treat a mammal, including a human, with an autoimmune disease (e.g. claimed uveitis) by administering DL111-IT (= STI959) as taught by Mistrello et al. to suppress the immune system (i.e. immunosuppressant effect). One would have been motivated to treat an autoimmune disease (e.g. uveitis) in a mammal in need of said treatment with DLT111-IT because Mistrella et al. suggest the need for more selective and less toxic immunosuppressant agents, as well as teach a mice model that is predictive for treating autoimmune diseases, while Hashimoto et al. and Lenardo separately suggest that immunosuppressants drugs that are useful in treating autoimmune disorders (e.g. rheumatoid arthritis) may be also useful for treating uveitis. One would have reasonably expected success by using (DLT111-IT) to treat uveitis because Mistrella teaches the use of DLT111-IT, in a dose that overlaps with the dose of DL111-IT (= ST1959) disclosed in the instant application, to treat arthritis and

Hashimoto and Leonardo discloses immunosuppressant drugs that treat arthritis and uveitis.

Thus, it would have been obvious to a person of skill in the art at the time the invention was made to create the instant claimed invention with reasonable predictability.

Relevant Art of Record

The below cited art made of record and relied upon is considered pertinent to applicant's invention.

Kawahito et al. teach that rat models appear to provide a powerful complementary approach to identify and characterize candidate genes that may contribute to autoimmune diseases in several species (abstract). Kawahito et al. teach that adjuvant-induced arthritis (AIA) in rats is a widely used autoimmune experimental model with many features similar to rheumatoid arthritis (RA) (abstract). Kawahito et al. also disclose study data of collagen-induced arthritis (CIA). Kawahito et al. teach that AIA predominantly involves T cell-mediated mechanisms, whereas CIA requires both humoral and cellular immunity (page 2, last paragraph, last line to page 3, line 1). Kawahito et al. teach that the quantitative trait loci (QTL) region on chromosome 4. *(Aia3/Cia3),* like the MHC, appears to be involved in several other autoimmune diseases in rats, including insulin-dependent diabetes, thyroiditis, and experimental autoimmune uveitis (abstract).

Conclusion

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 9 a.m. to 5:30 p.m. Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau, can be reached at 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http:pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 800-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

17 October 2008
/C. R./
Examiner, Art Unit 1611

/Sharmila Gollamudi Landau/

Supervisory Patent Examiner, Art Unit 1611